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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,151	04/14/2000	Thor Borgford	10447-011	1104

1059 7590 06/17/2003

BERESKIN AND PARR
SCOTIA PLAZA
40 KING STREET WEST-SUITE 4000 BOX 401
TORONTO, ON M5H 3Y2
CANADA

EXAMINER
LIU, SAMUEL W

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/551,151	BORGFORD, THOR	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-58* is/are pending in the application.

4a) Of the above claim(s) *42,44,46 and 48* is/are withdrawn from consideration.

5)☒ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40,41,43,45,47 and 49-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants' amendment filed 28 April 2003 (Paper No. 8) as to cancellation of claims 1-39 and addition of claims 40-58, and applicants' request for extension of time of one month filed 1 August 2001 (Paper No. 4) and extension of time of two months filed 28 April 2003 (Paper No. 7) have been entered.

Election/Restrictions

Applicants' election (filed 28 April 2003, Paper No.8) of Group II, claims 15-26 and 38 and additional election of SEQ ID NO:43 (linker peptide sequence), the ricin A chain, ricin B chain, matrix metalloproteinase and the viral protease from hepatitis C virus for patent examination with traverse is acknowledged. The traversal is on the ground(s) that the additional election should not be made with the restriction requirement while the election should be a species election (see the third paragraph, page 5). The applicant's argument is not persuasive since each SEQ ID NO sequences in claim 26 (previous) and claim 49 (current) are structurally distinct linkers not species. Furthermore, each protease sets forth in claim 22 (previous) and claim 45 (current) are distinct enzymes from one another, e.g., matrix metalloproteinase is enzymatically and mechanistically distinct from kallikrein protease in that the metalloproteinase cleaves preferentially one bond in native collagen from the N-terminus, at 775-Gly-Ile-776 in the alpha-1 (I) chain whereas the kallikrein protease selectively cleaves Arg (Lys) –Xaa bond.

Claims 42, 44, 46 and 48 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions on the basis of the elected proteins. Therefore, claims 40-41, 43, 45, 47 and 49-58 are under examination to the extent that they are drawn to the elected invention.

Examiner points out that "Group I" (line 4 from the bottom of page 4 of the restriction requirement mailed 1 February 2003) should be corrected to "Group II" in response to the applicant's comment (the first paragraph, page 6).

Specification/Claim Objections

The disclosure is objected to because of the following informalities:

In page 10, lines 31-34, the specification recites several peptide sequences, e.g., "SLLKSRMVPNFN" etc. Note the absence of "SEQ ID NO:_" for the corresponding sequences. The correction with regard to sequence identifier for each one of sequences is required under 37 C.F.R. 1.821. The same correction should be made throughout the specification.

In page 25, line 20, "HCMV" should be spelled out in full for the first instance of use. See also page 45, line 20, "DEAE"; page 57, line 19 "PCR"; page 61, line 26 "UV"; and page 62, line 8, "PVDF".

In page 59, line 17, "PCRs" should be changed to PCR reactions, and "98 degree C" and "98C" should be changed to "98 °C". The same change(s) should be made throughout the specification.

In page 61, line 4, "NaN3" needs a clarification.

In page 62, line 9, "ddH_2O" should be changed to "deionized distilled water".

In page 72, line 6, 30(C" should be changed to "30 °C". The same change(s) should be made throughout the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40-41 and 43 are rejected under 35 U.S.C. 102 (b) as being anticipated by Westby, M. et al. (*Bioconj. Chem.* (1992) 3, 375-381).

Westby et al. teach a recombinant protein comprising ricin A, ricin B and a linker sequence between ricin sequences A and B, wherein the linker comprises a trypsin-sensitive sequence for cleaving continuity between ricin A and ricin B (see abstract, page 375, and Figure 1), which meets the limitation set forth in claims 40, 41 and 43 of the instant application.

Claims 40-41, 43 and 54-58 are rejected under 35 U.S.C. 102 (b) as being anticipated by Borgford, T. et al. (WO 97/41233).

Borgford et al. teach a recombinant protein comprising an A chain of a ricin-like toxin, a B chain of a ricin-like toxin and a heterologous linker amino acid sequence which links the A and B chains, wherein the linker comprises a cleavage site for a viral protease (see patent claim 14), which meets the limitation of claim 40 of the current application.

Borgford et al. teach the A chain and the B chain are ricin A chain and ricin B chain, respectively (see the patent claims 15-16), as applied to claims 41 and 43 of the current application.

Also, Borgford et al. teach that the above-stated recombinant protein comprises a truncated ricin-like A chain or ricin A chain and a truncated ricin-like B chain or ricin B chain (see the second paragraph, page 14), which retains toxic activity; the Borgford et al. teaching meets the limitation set forth in claims 54-57 of the current application.

Further, Borgford et al. teach a pharmaceutical composition for treating a viral infection in a mammal comprising the recombinant protein of the patent claim 14 (see the foregoing statement) and a pharmaceutically acceptable carrier, diluent or excipients (see the patent claim 28 and page 22-23), as applied to claim 58 of the instant application.

Claim Rejection –Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Claims 40-41, 43 and 58 are rejected under the judicially created doctrine of the obviousness-type double patenting over claims 11and 19 of US Pat. No. 6531125. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claim 11 of US Pat. No. 6531125 discloses a recombinant protein comprising A and B chains of a ricin-like toxin and a linker peptide sequence that comprises a protease cleavage site,

wherein the protease is a viral protease. Thus, claim 11 discloses the common subject matter of claim 40 of the instant application.

Claims 41 and 43 are obvious over the disclosure of US Pat. No. 6531125 in light of that 6531125 patent teaches that ricin-like toxin encompasses ricin A and A chains (see column 11, lines 7-43, examples 1, and Figure 18). Claim 11 of US Pat. No. 6531125 is therefore an obvious variation of claims 41 and 43 of the instant application.

Claim 19 of US Pat. No. 6531125 is an obvious variation of claim 58 of the instant application.

It is therefore concluded that the claims of the present application are not patentably distinct from the claims of US Pat. No. 6531125.

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Provisional Rejection - Obviousness Type Double Patenting

Claims 40-41, 43, 45, 47, 49-53 and 58 of this application conflict with claims 15, 17, 18, 20, 22, 24, 26 and 40 of Application No. 10394511. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason

for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40-41, 43, 45, 47, 49-53 and 58 are provisionally rejected under the judicially created doctrine of double patenting over claims 15, 17, 18, 20, 22, 24, 26 and 40 of copending Application No. 09674266. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application

since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claims 15 and 17 of Application 10394511 disclose a recombinant protein comprising A and B chains of a ricin-like toxin and a linker peptide sequence that comprises a protease cleavage site, wherein the protease is a cancer, viral, fugal or a parasitic protease. Thus, claims 15 and 17 disclose the common subject matter of claim 40 of the instant application.

Claims 18, 20, 26 and 40 of Application 10394511 disclose the common subject matter of claims 41, 43, 49 and 58 of the instant application, respectively.

Claim 22 of Application 10394511 discloses that the above-mentioned cleavage site is matrix metalloproteinase specific, which is the obvious variation of claims 45 and 50-51 of the current application. Also, since claim 22 of Application 10394511 sets forth the cleavage site for human protease-specific antigen, claim 22 is an obvious variation of claim 52 of the current application.

Claim 24 of Application 10394511 discloses that the viral protease that recognizes the cleavage site is derived from a hepatitis C virus, which is an obvious variation of claims 47 and 53 of the current application.

Therefore, the instant application and Application No. 10394511 claims are obvious variations, and they are not patentably distinct from each other.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel Wei Liu, Ph.D.

June 5, 2003

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600